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Grassley Urges Drug Companies to Inform Employees About False Claims Act

WASHINGTON – Sparked by today's Schering-Plough settlement and others, Sen. Chuck Grassley, chairman of the Committee on Finance, urged drug companies to launch systematic campaigns preventing fraud in federal health care programs, including informing all employees about the False Claim Act.

"The government's settlement with Schering-Plough is a good example of the importance

of the False Claims Act's whistleblower provisions," Grassley said. "Without whistleblowers, this fraud might have never been exposed. Despite the value of these recoveries, some companies continue to be repeat offenders. With billions of dollars of profits at stake in the health care industry, more must be done to deter the perception that fraud settlements are the cost of doing business with the federal government. Taxpayers can't continue to subsidize those drug companies that rely on illgotten profits. That's why I'm urging all the major drug companies to launch meaningful anti-fraud programs, with informing all employees about the False Claims Act as the centerpiece."

Federal prosecutors announced today that Schering Sales Corporation, a subsidiary of drug manufacturer Schering-Plough Corporation, has agreed to plead guilty to criminal charges and to pay a fine of \$52.5 million. Schering-Plough Corporation has agreed to pay more than \$290 million to resolve its civil liabilities in connection with its illegal and fraudulent pricing of its blockbuster drug, Claritin.

Grassley is the Senate author of the 1986 whistleblower amendments strengthening the False Claims Act. The text of his letter to the nation's major drug companies follows. In addition to Schering-Plough Corporation, the drug makers who received a letter from Grassley were Pfizer, Inc., GlaxoSmithKline, Johnson & Johnson, Merck & Co., Inc., AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Novartis Pharmaceuticals Corporation, Amgen, Inc., Wyeth Pharmaceuticals, Eli Lilly & Company, Aventis Pharmaceuticals Inc., Abbott Laboratories, Hoffmann-La Roche Inc., TAP Pharmaceutical Products Inc., Boehringer Ingelheim Pharmaceuticals, Inc., Forest Pharmaceuticals, Inc., Sanofi-Synthelabo and Eisai, Inc.

VIA FACSIMILE (908) 298-5310

ORIGINAL BY U.S. MAIL

Mr. Paul A. Weissman Schering-Plough Corporation 2000 Galloping Hill Road, K-6-1 Kenilworth, New Jersey 07033

Dear Mr. Weissman:

As the principal sponsor of the 1986 Amendments to the False Claims Act (FCA), I have witnessed the FCA's remarkable success in bringing health care fraud to the attention of the federal government. As you may know, the FCA establishes liability for contractors that commit fraud by submitting false or fraudulent claims for reimbursement to the federal government and permits whistleblower suits.

According to a report released by Taxpayers Against Fraud, a national non-profit organization focused on enforcement of the FCA, the net recoveries to the federal government from civil health care fraud during the period from 1999-2003, amounted to \$5.26 billion. While this remarkable return of taxpayer dollars is evidence that the FCA and other enforcement mechanisms continue to work in many important respects, I have watched with dismay as many of the leading companies in the health care industry have been implicated in systematic, large-scale fraud, involving billions of dollars.

While we have the best health care system in the world, a few bad actors can result in billions in fraud and taint the perception of entire sectors of the health care field. Current recoveries may represent just the tip of the iceberg and federal investigators and/or whistleblowers are forever chasing after the next fraudulent scheme.

Many of the companies that have settled fraud enforcement matters with the Department of Health & Human Services (HHS), Office of Inspector General (OIG), are required to maintain ethics and compliance programs. The HHS-OIG has provided model compliance program guidance to some providers in the health care community, including final guidance for hospitals and draft guidance for the pharmaceutical manufacturers. In its draft guidance to the pharmaceutical manufacturers, the OIG says that, among other elements, every effective compliance program should include:

[A]s a first step, a good faith and meaningful commitment on the part of the company's management will substantially contribute to [a compliance] program's successful implementation. . . . [T]hat commitment should filter down through management to every employee and contractor of the pharmaceutical manufacturer, as applicable for the particular individual. At a minimum, a comprehensive compliance program should include . . . [t]he development and distribution of written standards of conduct, as well as written policies, procedures and protocols that verbalize the company's commitment to compliance (e.g., by including adherence to the compliance program as an element in evaluating management and employees) and address specific areas of potential fraud and abuse, such as the reporting of pricing and rebate information to the Federal health care programs, and sales and marketing practices.

While your company may or may not be subject to a mandatory compliance program, I ask that you take seriously the need to articulate written standards of corporate conduct and educate employees about health care fraud. I can think of no better way to send your employees the message that your company aims to comply with the law and will not tolerate fraudulent activity than to arm them with knowledge about the FCA and other health care enforcement mechanisms.

Creating awareness among your company's employees that they may file suit under the FCA would seem to be a step in the right direction. Please advise whether your company would voluntarily provide basic information about the FCA in some meaningful way to your employees.

As Chairman of the Senate Committee on Finance, I request that you respond by August 16, 2004. Thank you in advance for promptly complying with this request.

Sincerely,

Charles E. Grassley

Chairman